Application/Control Number: 10/711,327 Page 2

Art Unit: 1795

DETAILED ACTION

Summary

- 1. This Office Action is in response to the Election filed April 30, 2008 in which the applicant has elected Invention I, claims 1-5 and 9.
- 2. Claims 1-5 and 9 are currently pending and have been fully considered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 4. Claims 1-5 and 9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by TIXIER et al. (Catching and Attaching Cells Using an Array of Microholes; 1st Annual International IEEE-EMBS Special Topic Conference on Microtechnologies in Medicine & Biology, October 12-14, 2000 [from applicant IDS filed 9/15/2004]).
 - a. With regards to claim 1, TIXIER et al. discloses a device for creating microgradients in solution comprising a microfluidic channel with openings at each end and two or more apertures in the channel walls (FIG. 6(a) discloses at least 4 apertures in which one at each end can be the openings and the apertures in between along the length of the channel can be the two or more apertures), electrodes (FIG. 1 "microelectrodes") placed in or near the openings at either end of the channel, and an electrical power supply

Application/Control Number: 10/711,327

Page 3

Art Unit: 1795

(inherent in order for electrodes to apply voltage; see 1st sentence page 37) connected to the electrodes.

- b. With regards to claim 2, TIXIER et al. discloses a device wherein the power supply is connected to the electrodes such that it is structurally capable of providing several distinct current paths from one end of the channel to the other and current flows along all of these paths when an electric field is applied along the channel by the combination of the power supply and the electrodes (FIG. 1 discloses multiple microelectrodes designed to provide multiple current paths).
- c. With regards to claim 3, TIXIER et al. discloses a device wherein the power supply is connected to the electrodes such that it is structurally capable of providing simultaneous flow of fluid occurs through two or more of the apertures and a chemical concentration gradient is formed near the apertures (FIG. 1 discloses genes to be inserted flowing through apertures into the cells in which a chemical gradient is formed near the apertures, such as from one side of the aperture "cell side" to the other side "channel side").
- d. With regards to claim 4, TIXIER et al. discloses a device wherein the dimensions of the apertures are between about 0.1 and ten microns across (such as 6 microns diameters, 2nd paragraph, column 1 page 39), a traverse dimension to the length of the channel is between 0.1 and one hundred microns (FIG·6(a) which appears to be to scale discloses holes with 6 micron wide diameters in which the width of the channel is inherently in the range of 0.1 to one hundred microns), and a length of the channel is between about 10 microns and 10 millimeters (FIG. 6(a) which appears to be to scale

Application/Control Number: 10/711,327

Art Unit: 1795

Page 4

discloses holes with 6 micron wide diameters in which the length of the channel, which can consist of 4 microholes [the first being the inlet, two apertures, and an outlet] is greater than 10 microns long and smaller than 10 millimeters long).

- e. With regards to claim 5, TIXIER et al. discloses a device further comprising structures that form indentations in the channel near the apertures (walls near "microhole" on either side form indentations, FIG. 2), such indentations being approximately the size of a living cell (FIG. 2).
- f. With regards to claim 9, TIXIER et al. discloses a microfluidic device comprising, a microfluidic channel with an inlet, outlet, and two or more apertures in the channel walls (FIG. 6(a) discloses at least 4 apertures in which one at each end can be the inlet or outlet and the apertures in between along the length of the channel can be the two or more apertures) structurally capable of defining a flow path for a fluid having a known concentration of a selected chemical and structurally capable of providing fluid communication between the channel and a reservoir containing a sample solution (FIG. 1 discloses reservoir above channels where cell solution is), electric field means (FIG. 1 "microelectrodes") provided and is structurally capable of inducing electroosmotic flow along the flow path, and means for applying pressure (gravitational forces on the fluid at the inlet, outlet, and apertures) to the fluid in the flow path which is structurally capable of providing flow such that fluid flows simultaneously out of the channel such that cells cultured near each aperture are exposed to a separate concentration of the chemical corresponding to the location of the aperture along the concentration gradient. Regarding claims which contain various process or intended use limitations which do not further

Art Unit: 1795

delineate the structure of the claimed apparatus from the structure of the prior art, because these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. These recited process or use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey 152 USPQ 235 (CCPA 1967); and In re Otto, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See In re Danly 120 USPO 528, 531 (CCPA 1959); and Hewlett-Packard Co. v. Bausch and Lomb, Inc., 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The courts have held that expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. See Ex parte Thibault, 164 USPQ 666, 667 (BPAI 1969). The courts have held that inclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims. See In re Young, 75 F.2d 996, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 312 F.2d 937, 136

Application/Control Number: 10/711,327 Page 6

Art Unit: 1795

USPQ 458, 459 (CCPA 1963)). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all the structural limitations of the claim. See Ex parte Masham, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Response to Arguments

- 5. Applicant's arguments filed April 30, 2008 traversing the Restriction Requirement have been fully considered but they are not persuasive.
 - a. Applicant argues that the restriction requirement is not proper because evidence that a serious search and examination burden has not been provided and the examiner has "merely presented a set of form paragraphs". However, this argument is not persuasive. The set of form paragraphs presented in examples (a)-(e) are presented to demonstrate evidence that a serious search and examination burden indeed exist in certain hypothetical patent application. In the restriction requirement sent April 4, 2008, it is stated that the inventions of groups I and II can be classifiable in different class/subclasses in which the examination of group II may require search in a class/subclass that the invention of group I would not. Hence, applicant is advised to refer to the form paragraph presented in the Restriction Requirement sent April 4, 2008, (a) on page 3, which clearly demonstrates evidence that a serious search and examination burden would exist if the inventions have acquired a separate status in the art in view of their different classification.

Art Unit: 1795

Conclusion

Page 7

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DUSTIN Q. DAM whose telephone number is (571)270-5120. The examiner can normally be reached on Monday through Thursday, 7:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571)272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/ Supervisory Patent Examiner, Art Unit 1753

dd

September 2, 2008